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## SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 3700 ULTRA-SENSITIVE UNCONJUGATED ESTRIOL  
RIA Kit  
Classification Name: Radioimmunoassay, UNCONJUGATED ESTRIOL  
Analyte Code and Name: Unconjugated Estriol  
Regulatory Class: I

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The DSL Ultra-Sensitive Unconjugated Estriol RIA kit was developed for the quantitative measurement of Unconjugated Estriol in human serum. The RIA format is a competitive binding protein assay. Radio-labeled Unconjugated Estriol competes with un-labeled Unconjugated Estriol in the serum sample for binding sites on the antibody coated tubes. Separation of free from bound Unconjugated Estriol is achieved by decanting the coated tubes after incubation. The resultant is analyzed in a gamma counter for bounds counts per minute. The amount of radio-labeled estriol bound to the antibody is inversely proportional to the concentration of the estriol present in the sample.

The DSL ULTRA-SENSITIVE UNCONJUGATED ESTRIOL RIA assay is intended for the quantitative determination of Unconjugated Estriol in human serum. The measurement of Unconjugated Estriol is used as a diagnostic aid in the diagnosis and treatment of fetoplacental distress.

The DSL ULTRA-SENSITIVE UNCONJUGATED ESTRIOL RIA is substantially equivalent to the DPC FREE ESTRIOL RIA.

To demonstrate substantial equivalence between the two assays, patient samples (n=126) were collected and assayed using both methods. Samples were chosen based on expected Unconjugated Estriol levels so that samples with low, intermediate and high levels would be evaluated. Linear regression analysis of the results obtained for the comparison gave the equation  $Y=0.58(X) + -0.03$  with a correlation coefficient of  $(r) = 0.97$ .